NASA Procedural Requirements

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COMPLIANCE IS MANDATORY

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Request Notification of Change (NASA Only)

Subject: Health and Medical Requirements for Human Space Exploration

Responsible Office: Office of the Chief Health & Medical Officer

Appendix D. Transition to Medical Practice

Note: The Transition to Medical Practice (TMP) review process is designed to assess the effectiveness and operational readiness of human health-related research and technology products and deliverables. It provides a clear channel for human health and medical-related flight and ground research results for transition to tools available to support Agency human space flight programs.

The TMP review process shall be conducted according to the HMTA established below and applied to newly proposed medical procedures, practices, processes, countermeasures, or technologies resulting from NASA-sponsored research that are designed to maintain the health, and/or support the medical care, of space flight crews.

1. The submitting organization presents a proposal for TMP review of a research or technology deliverable or product to the appropriate JSC configuration control board (CCB) for review and recommendation to the JSC CMO.

2. Upon recommendation by a JSC CCB, the submitting organization provides a written request for TMP review of a research or technology deliverable or product to the JSC CMO for review.

3. The JSC CMO recommends to the NASA CHMO that a panel be convened.

4. A panel is convened to review each deliverable or product. Review panel members will have the appropriate aerospace medicine and operational expertise and will include representation from the AMB.

5. The submitting organization provides the following documentation to the JSC CMO and the NASA CHMO in advance of the TMP panel review:

(1) A detailed description of the deliverable or product, its intended use or application, and a description of how the deliverable or product addresses a NASA-identified critical risk, medical issue, or application.

(2) Data demonstrating the efficacy, effectiveness, or utility of the deliverable or product.

(3) Data demonstrating the operational validation of the deliverable or product.

(4) An implementation plan of how the product or deliverable is to be used or applied (e.g., protocol, dosing regime, scope of use, etc.).

(5) An analysis of the mission resources (e.g., crew time, volume, power, etc.) necessary to implement the product or deliverable.

6. The TMP panel provides a recommendation for consideration by the JSC CMO and the NASA CHMO.

7. The NASA CHMO provides recommendations to the MPB for final consideration and approval.

8. The MPB shall provide one of the following recommendations:

* Approve: The CHMO will certify the product or deliverable for NASA medical practice.

* Approve with Revision: The CHMO will certify the product or deliverable as NASA medical practice, with revisions to the implementation plan or scope of use, as recommended by the TMP review panel.

* Defer: A decision regarding the product or deliverable will be deferred until additional information can be supplied to the review panel. This may be a request for additional supporting documentation or for additional data collection and/or experimentation.

* Reject: The product or deliverable will not be certified as NASA medical practice.

9. The OCHMO shall convey, in writing, the results of the TMP review to the submitting organization and to the JSC CMO.

10. Once approved, the product or deliverable will be available for use according to established NASA policy.

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